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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/763,628

01/23/2004

Carter R. Anderson

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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/25/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/763,628	<b>Applicant(s)</b> ANDERSON ET AL.	
	<b>Examiner</b> Jagadishwar R. Samala	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>04/29/04; 12/12/05 &amp; 01/17/06</u> | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### **Election Acknowledged**

1. Applicant's election with traverse of invention group II in the reply filed on December 07, 2006 is acknowledged. The traversal is on the ground(s) that applicant's arguments, the claimed invention of group I and II are not patentably distinct (i.e., "must practiced together", see page 9, line 21). This is not found persuasive because claims 1-9, 25-33 and claims 10-24 differ in scope as indicated by their distinct modes of operation. As evidenced by (US 5,149,538 and US 5,236,714), the use of composition containing the abusable substance and an amount of an antagonist therefor sufficient to substantially negate the pharmacological effect of an abusable substance to the body. The requirement is still deemed proper and is therefore made FINAL

### **Status of Application**

2. Claims 1-33 are pending and claims 10-24 are elected and under examination. Claims 1-9 and 25-33 have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "first user" in claim 10 is a relative term which renders the claim indefinite. The term "first user" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10,11,15-19, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sackler (US 2003/0068392 A1 here after '392) in view of Stanley et al. (US 6,261,595 B1 here after '595)

Claims 10,11,15-19, 23 and 24 are drawn to a system for skin-worn transdermal patch devices containing abusable substances, a layer containing anti-abuse substance such as antagonists, irritants or activated carbon and closure means for closing said container.

The '392 patent teaches a transdermal dosage form of an abusable substance including natural and synthetic opioid such as fentanyl, an antagonist for an anti-abusable substance such as naloxone or naltrexone (see 0078, and 0058).

The '392 patent although teaches a transdermal dosage form of an abusable substance in combination with an amount of antagonist for said abusable substance sufficient to substantially negate the pharmacological effect of the abusable substance, fail to teach specifically a closure means for closing the container or pouch, so that the container can also provide a closed system for disposing of the used skin-worn patch.

However it is well known in the art that a transdermal patch as well as all medicine containing formulas are protected or enclosed in a container. As evidenced by the '595 patent teaching a transdermal drug delivery system comprising a dermal drug delivery patch and a heating element pouch securable to the dermal drug delivery patch (see abstract). Although the closure means for closing the container and also aiding in disposing of skin-worn patch as required by instant claim 10, as not been explicitly mentioned, because the pouch of the transdermal drug delivery patch taught by '595 assist in the achievement of desired functional activity of transdermal patch, so that the container or pouch can also serve as a closed system for disposing of the used skin-worn patch.

It would have been obvious to one of ordinary skill in the art to modify the transdermal dosage form disclosed by '392, to include a transdermal drug delivery system comprising a dermal drug delivery patch and a pouch closure means as an additional component for disposing of the used skin-worn patch. One of ordinary skill in

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the art would have been motivated to include the pouch or compartment in the transdermal dosage form disclosed by '392, because the teaching of '595 while having a similar effect for reducing potential for substance abuse, provide an additional and separate advantage as compared to the transdermal dosage form disclosed by '392.

5. Claims 12-14 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sackler (US 2003/0068392 A1 here after '392) in view of Schoendorfer et al. (US 5,899,856 here after '856).

Claims 12-14 and 20-23 are drawn to a system for skin-worn transdermal patch devices containing anti-abuse substance such as antagonists, irritants and activated carbon.

The '392 patent teaches a transdermal dosage form containing an antagonist for an anti-abusable substance such as naloxone or naltrexone and an irritant such as capsaicin (see 0058 and 0052).

The '392 patent although teaches a transdermal dosage form of an abusable substance in combination with an amount of antagonist and irritant for said abusable substance sufficient to substantially negate the pharmacological effect of the abusable substance, fail to teach specifically a activated charcoal as an anti-abuse substance. However, a charcoal-containing binding or adsorption pad in a dermal patch to be worn on the skin is well known in the art as shown by '856.

The '856 patent teaches a transdermal patch that includes a charcoal containing adsorption pad for collecting vapor phase perspiration from a subject's skin and retaining a vapor phase analyte (see column 4, lines 37-44).

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It would have been obvious to one of ordinary skill in the art to modify the transdermal dosage form of an abusable substance disclosed by '392 to include activated charcoal as an additional anti-abuse substance because '856 teaches that activated charcoal are useful for collecting vapor phase perspiration from a subject's skin because it provide the advantage for determining the presence of an analyte in perspiration of a subject mammal. One of ordinary skill in the art would have been motivated to include the activated charcoal as an additional anti-abuse substance in the transdermal dosage form disclosed by '392. It is well documented in the prior art the use of activated charcoal as a binding material. For e.g. (US 4,732,153) discloses a transdermal dossier to monitor exposure to chemical agents by providing an unbroken fluid link between tissue fluids in the skin and the fluid collecting component which may include activated charcoal as a binding material (see column 3, lines 12-18).

### ***Conclusion***

1. No claims are allowed at this time.

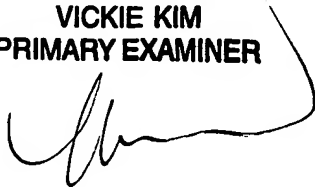
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**VICKIE KIM  
PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read 'Vickie Kim', written over the printed name and title.

Jagadishwar R Samala  
Examiner  
Art Unit 1618

sjr